Louis H. Weinstein (LW 7868)
Andrew J. Miller (AM 8160)
BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078
(973)379-4800
Attorneys for Defendants and
Counterclaim Plaintiffs
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E, INC.,	07-CV-6790 (CM)(GWG)
Plaintiffs and Counterclaim Defendants,	
v.	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.	**ELECTRONICALLY FILED**
Defendants and Counterclaim Plaintiffs.	

FOURTH DECLARATION OF HARRY G. BRITTAIN, Ph.D., FRSC
(Filed in Opposition to AstraZeneca's Motion To Strike)

1. I am the same Harry G. Brittain who submitted the Second Declaration of Harry G. Brittain in this litigation, a Declaration which I prepared to support DRL's Motion for Summary Judgment.

2. I also submitted the Third Declaration of Harry G. Brittain in this litigation, a Declaration that I prepared to support DRL's Summary Judgment Reply.

3. I discussed my credentials and professional experience in paragraphs 1-8 of my Second Declaration. A summary of my credentials and professional experience and a copy of my curriculum vitae were attached to my Second Declaration as Exhibit A, and those documents are also attached to this Declaration as Exhibit A.

4. The statements I make in this Declaration are based on my personal knowledge.

5. In connection with this litigation, counsel for DRL asked me for my opinions regarding the alleged infringement of DRL's omeprazole magnesium product in view of United States Patents 5,900,424 and 5,690,960.

6. In coming to the opinions expressed in my Second Declaration, it was necessary for me to know certain facts concerning the processes about which I was being asked to opine. The facts that I wanted to know included factual details such as temperature, pressure, time, weight, reagents, equipment, and processing steps. These are the types of facts that an expert in my field would reasonably rely upon when forming an opinion about a pharmaceutical process.

7. In coming to the opinions expressed in my Second Declaration, I relied in part on the detailed facts regarding temperature, pressure, time, weight, reagents, equipment, and processing steps that were listed in the two summaries presented as part of DRL's Answer to Interrogatory No. 10. A copy of that Interrogatory Answer was attached at pages 9-16 of Exhibit 6 to the Second Declaration of Louis H. Weinstein that was filed in this litigation.

The opinions stated in my Second Declaration were directed to the processes described by the detailed facts listed in those two summaries.

8. The detailed facts regarding temperature, pressure, time, weight, reagents, equipment, and processing steps listed in those two summaries are the type of factual details that an expert in my field would reasonably rely upon in forming opinions as to whether a pharmaceutical process did or did not infringe patent claims directed to pharmaceutical manufacturing methods.

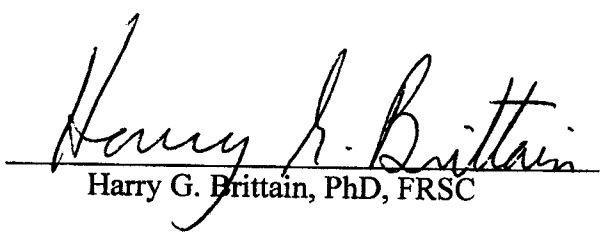
9. After submitting my Second Declaration I was informed by counsel for DRL that AstraZeneca had made an evidentiary objection to my Second Declaration on the ground that I should have based my opinion on the documents contained in the Drug Master File (DMF) and Abbreviated New Drug Application (ANDA) filed by DRL.

10. In preparing my Third Declaration I did review and rely upon the sections of DRL's DMF and ANDA which contained the facts that were relevant to the opinions stated in my Second Declaration.

11. As stated in paragraphs 4 and 8 of my Third Declaration, my opinions regarding DRL's bulk drug substance, DRL's finished drug product, and DRL's manufacturing processes remained the same following my review of the relevant portions of DRL's DMF and ANDA.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information and belief.

Signed,



Harry G. Brittain, PhD, FRSC

Date: September 3, 2008

CERTIFICATE OF SERVICE

I certify that on this 5th day of September, 2008, I caused a true and correct copy of the FOURTH DECLARATION OF HARRY G. BRITTAIN, Ph.D., FRSC (Filed in Opposition to AstraZeneca's Motion to Strike) to be served upon counsel for AstraZeneca in the following manner:

By ECF, E-MAIL AND FEDERAL EXPRESS

Errol B. Taylor, Esq.
Milbank, Tweed, Hadley &
McCloy LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
Facsimile: 212-530-5219

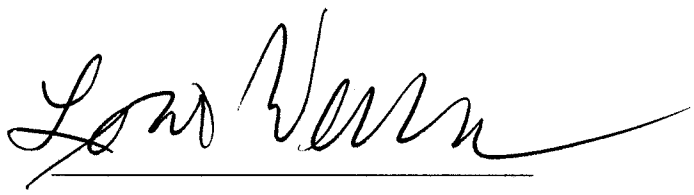


EXHIBIT A

Harry G. Brittain, PhD, FRSC

Center for Pharmaceutical Physics
10 Charles Road
Milford, NJ 08848

tel.: (908)-996-3509 fax: (908)-996-3560

Email: hbrittain@centerpharmphysics.com

Education

Ph.D. (Physical Chemistry)	City University of New York (February, 1975)
M.A. (Physical Chemistry)	Queens College (June, 1972)
B.A. (Chemistry)	Queens College (June, 1970)

Experience (Industrial)

Center for Pharmaceutical Physics (Milford, NJ)

Institute Director (May 1999 to present)

Providing consultation in all areas of pharmaceutical physics and physical pharmacy, including preformulation, formulation design, and product characterization. Special areas of expertise are in the polymorphism of drug substances, and in the physical characterization of pharmaceutically related materials. Also consult in subjects dealing with chirality and optically active substances, with a special interest in enantiomeric drug substances.

The Center for Pharmaceutical Physics features a full array of equipment suitable for contract work and research in solid state science and spectroscopy. On site is instrumentation that measures x-ray powder diffraction, differential scanning calorimetry, Fourier-transform infrared absorption spectroscopy, kinetic and equilibrium solubility, surface tension, conductivity, powder characteristics, UV/VIS absorption and diffuse reflectance, polarimetry, fluorescence, and circularly polarized luminescence.

Discovery Laboratories, Inc. (formerly Acute Therapeutics, Inc.; Doylestown, PA)

Vice President, Pharmaceutical Development (November 1996 to April 1999)

Held responsibility for all non-clinical aspects of drug development at DLI, and managed the entire range of analytical, pharmaceutical, and chemical development efforts. Also held responsibility for the design, formulation, and development of all new products.

Ohmeda Pharmaceutical Products Division, Inc. (Murray Hill, NJ)

Director, Pharmaceutical, Analytical, and Chemical Development (July 1994 to October 1996)

Responsible for all latter-stage aspects of drug development at Ohmeda, managing the Analytical, Pharmaceutical, and Chemical Development groups. Coordinated the CMC development of parenteral products from product concept to drug registration.

Bristol-Myers Squibb Pharmaceutical Research Institute (New Brunswick, NJ)
Senior Research Fellow (May 1993 to June 1994)
Associate Director (December 1990 to April 1993)
Senior Group Leader (April 1989 December 1990)
Group Leader (November 1987 to April 1989)
Research Fellow (November 1986 to November 1987)
Senior Research Investigator (November 1985 to November 1986)
Held positions entailing the supervision of groups engaged in physical analytical chemistry, physical pharmacy, bulk drug analysis, and dosage form analysis.

Experience (Academic)

Rutgers University (Piscataway, NJ)
Adjunct Associate Professor of Pharmaceutics (July 1993 to June 1997; October 2001 to June 2002)
Taught sections of the Advanced Pharmaceutics course, and co-sponsored the thesis work of one graduate student

Lehigh University (Bethlehem, PA)
Visiting Research Scientist (June 1998 to June 2001)
Act as consultant to the Department of Chemistry for the design of short courses of interest to the pharmaceutical industry, and have taught in the Distance Education program
Adjunct Associate Professor of Chemistry (Fall 1999 semester)
Taught Chemistry-31, "Equilibria in Chemical Systems"

Seton Hall University (South Orange, NJ)
Associate Professor of Chemistry, with Tenure (September 1982 to October 1985)
Assistant Professor of Chemistry (September 1979 to August 1982)
Taught numerous courses in physical, general, and inorganic chemistry, and graduated eight Ph.D. and four M.S. students

Ferrum College (Ferrum, VA)
Assistant Professor of Chemistry (September 1976 to August 1979)
Taught courses in general, analytical, and environmental chemistry

University of Virginia (Charlottesville, VA)
Postdoctoral Research Fellow (February 1975 to August 1976)
Worked on chiroptical spectroscopy investigations in collaboration with Professors F.S. Richardson and P.N. Schatz

Awards

Teacher-Scholar of the Camille and Henry Dreyfus Foundation, 1980-85

Innovation Quality/Productivity Award, sponsored by Bristol-Myers Squibb Co., 1990

Fellow of the American Association of Pharmaceutical Scientists, 1991

Research Achievement Award, APQ Section of the American Association of Pharmaceutical Scientists, 1998

Author of the most frequently downloaded article ("Polymorphism and Solvatomorphism 2005") that had been published in the *Journal of Pharmaceutical Sciences* during 2007

Editorial Responsibilities

(a) Editorial Advisory Board Membership

Journal of Coordination Chemistry, April 1986 to July 1994
Analytical Profiles of Drug Substances, May 1988 to May 1991
Pharmaceutical Research, February 1990 to June 1995
Instrumentation Science & Technology, June 1990 to December 2001
Journal of Pharmaceutical and Biomedical Research, January 1992 to April 1993
Pharmaceutical Technology, January 1993 to present
Chirality, January 1995 to December 2007
Pharmaceutical Research, January 1998 to December 2005
AAPS PharmSci, January 1999 to December 2007
Journal of Pharmaceutical Sciences, January 1999 to December 2005
Journal of Pharmaceutical and Biomedical Research, January 1999 to December 2002
AAPS PharmSciTech, August 2001 to present
Encyclopedia of Pharmaceutical Technology, June 2003 to present
Drugs and the Pharmaceutical Sciences (Informa Press book series), April 2005 to present

(b) Publication Management

Journal of the Electrochemical Society, Divisional Editor, January 1984 to December 1987
Analytical Profiles of Drug Substances and Excipients, Editor, June 1991 to December 2002
Journal of Pharmaceutical and Biomedical Research, Assistant Editor, January 1994 to December 1998
American Association of Pharmaceutical Sciences Publications Board, Member At Large, 2001 to present
Pharmaceutical Development and Technology, Book Review Editor, November 1998 to present
Profiles of Drug Substances, Excipients, and Related Methodology, Editor, January 2003 to present
Pharmaceutical Research, Field Editor for Preformulation, January 2003 to December 2005
Journal of Pharmaceutical Sciences, Associate Editor for Physical Pharmacy, January 2006 to present

Scholarly Activities

Published 18 edited books since 1992

Published over 285 research papers and book chapters since 1975

Presented over 120 invited lectures since 1987

Taught over 30 short-courses since 1988

Compendial (United States Pharmacopeia) Activities

Member: USP Advisory Panel I on Physical Test Methods, formed at the recommendation of the Excipients Subcommittee (May 1991 to August 1995)

Member: USP Advisory Panel II on Physical Test Methods, formed at the recommendation of the Excipients 2 Subcommittee (August 1995 to April 2000)

Member: USP Committee of Revision. Duties were divided between the Excipients 2 Subcommittee (2/3 effort) and the Chemistry 4 Panel (1/3 effort) (August 1995 to April 2000)

Chairman: USP EMC Expert Committee (Excipients: Monograph Content), April 2000 to April 2005.

Member: USP Excipients General Chapters Expert Committee, April 2005 to present.

Professional Societies

American Association of Pharmaceutical Scientists (Fellow)

American Chemical Society (member)

Royal Society of Chemistry (Fellow)

Controlled Release Society (member)

Parenteral Drug Association (member)

International Centre for Diffraction Data (member)

Society of Fluorescence (member)

Books Edited by Harry G. Brittain, Ph.D.

(a) Published Volumes

(1) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **21**
ISBN 0-12-260821-6
Academic Press, San Diego, 1992

(2) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **22**
ISBN 0-12-260822-4
Academic Press, San Diego, 1993

(3) N. Purdie and H.G. Brittain, eds.
Analytical Applications of Circular Dichroism
ISBN 0-444-89508-6
Elsevier Science Publishers, Amsterdam, 1994

(4) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **23**
ISBN 0-12-260823-2
Academic Press, San Diego, 1994

(5) H.G. Brittain, ed.
Physical Characterization of Pharmaceutical Solids
ISBN 0-8247-9372-2
Marcel Dekker, New York, 1995

(6) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **24**
ISBN 0-12-260824-0
Academic Press, San Diego, 1996

(7) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **25**
ISBN 0-12-260825-9
Academic Press, San Diego, 1998

(8) H.G. Brittain, ed.
Polymorphism in Pharmaceutical Solids
ISBN 0-8247-0237-9
Marcel Dekker, New York, 1999

(9) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **26**
ISBN 0-12-260826-7
Academic Press, San Diego, 1999

(10) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **27**
ISBN 0-12-260827-5
Academic Press, San Diego, 2001

(11) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **28**
ISBN 0-12-260828-3
Academic Press, San Diego, 2001

(12) H.G. Brittain, ed.
Analytical Profiles of Drug Substances and Excipients, volume **29**
ISBN 0-12-260829-1
Academic Press, San Diego, 2002

(13) H.G. Brittain, ed.
Profiles of Drug Substances, Excipients, and Related Methodology, volume **30**
ISBN 0-12-260830-5
Elsevier Academic Press, Amsterdam, 2003

(14) H.G. Brittain, ed.
Profiles of Drug Substances, Excipients, and Related Methodology, volume **31**
ISBN 0-12-260831-3
Elsevier Academic Press, Amsterdam, 2004

(15) H.G. Brittain, ed.
Profiles of Drug Substances, Excipients, and Related Methodology, volume **32**
ISBN 0-12-260832-1
Elsevier Academic Press, Amsterdam, 2005

(16) H.G. Brittain
Spectroscopy of Pharmaceutical Solids
ISBN 1-57444-893-5
Taylor & Francis, New York, 2006

(17) M.C. Adeyeye and H.G. Brittain, eds.
Preformulation in Solid Dosage Form Development
ISBN 0-8247-5809-9
Informa Healthcare Press

(18) H.G. Brittain, ed.
Profiles of Drug Substances, Excipients, and Related Methodology, volume **33**
ISBN 0-12-260833-9
Elsevier Academic Press, Amsterdam, 2007

(b) Book Projects Currently in Press

(19) H.G. Brittain, ed.
Profiles of Drug Substances, Excipients, and Related Methodology, volume **34**
To be published by Elsevier Academic Press

(c) Book Projects under Development

(20) H.G. Brittain, ed.
Profiles of Drug Substances, Excipients, and Related Methodology, volume **35**
To be published by Elsevier Academic Press

(21) H.G. Brittain, ed.
Polymorphism in Pharmaceutical Solids, 2nd edition
To be published by Informa Healthcare Press

Research Publications and Book Chapters Published by Harry G. Brittain

(1) H.G. Brittain
"Proton Magnetic Resonance Spectrum of Magnesium Acetylacetonate in Deuterochloroform: Evidence for Conformational Equilibrium"
Inorg. Chem., **14**, 2858 (1975)

(2) T.L. Miller, D.J. Nelson, H.G. Brittain, F.S. Richardson, R.B. Martin, and C.M. Kay
"Calcium Binding Sites of Rabbit Troponin and Carp Parvalbumin"
FEBS Lett., **58**, 262 (1975)

(3) H.G. Brittain and R.L. Disch
"The He(I) Photoelectron Spectra of Some Bivalent Transition Metal β-Diketonate Complexes"
J. Electron Spect. Rel. Phen., **7**, 475 (1975)

(4) H.G. Brittain, F.S. Richardson, R.B. Martin, L.D. Burtnick, and C.M. Kay
"Circularly Polarized Emission of Tb(III) Substituted Bovine Cardiac Troponin-C"
Biochem. Biophys. Res. Comm., **68**, 1013 (1976)

(5) H.G. Brittain and F.S. Richardson
"pH Dependence of Circularly Polarized Emission and Total Emission from Eu(III)/L-Malic Acid and Eu(III)/L-Malic Acid/Tb(III) Complexes in H_2O and D_2O Solutions"
Inorg. Chem., **15**, 1507 (1976)

(6) H.G. Brittain and F.S. Richardson
"Circularly Polarized Emission Studies on the Chiral Nuclear Magnetic Resonance Lanthanide Shift Reagent tris[3-trifluoroacetyl-*d*-camphorato]-Eu(III)"
J. Am. Chem. Soc., **98**, 5858 (1976)

(7) H.G. Brittain, F.S. Richardson, J.P. Jasinski, W.C. Yeakel, and P.N. Schatz
"Magnetic Circularly Polarized Emission from Crystalline Cs_2ZrCl_6:Re(IV)"
J. Phys. Chem., **80**, 2228 (1976)

(8) H.G. Brittain and F.S. Richardson
"Emission Titration Studies on the Formation of $Eu(FOD)_3$:Substrate Adducts in Solution"
J. Chem. Soc. Dalton Trans., 2253 (1976)

(9) H.G. Brittain, F.S. Richardson, and R.B. Martin
"Tb(III) Emission as a Probe of Ca(II) Binding Sites in Proteins"
J. Am. Chem. Soc., **98**, 8255 (1976)

(10) H.G. Brittain and F.S. Richardson
"Circularly Polarized Emission Studies of Chiral and Achiral Eu(III) β-Diketonate Complexes in an Optically Active Solvent"
J. Am. Chem. Soc., **99**, 65 (1976)

(11) H.G. Brittain and F.S. Richardson
"Solvent Induced Circularly Polarized Emission from Fluorescein"
J. Phys. Chem., **80**, 2590 (1976)

(12) W.C. Yeakel, R.W. Schwartz, H.G. Brittain, J.L. Slater, and P.N. Schatz
"Magnetic Circularly Polarized Emission Magnetic Circular Dichroism of Resolved Vibronic d-Lines of Cs_2GeF_6:Mn(IV)"
Mol. Phys., **32**, 1751 (1976)

(13) H.G. Brittain and F.S. Richardson
"Intermolecular Energy Transfer Between $Tb(THD)_3$ and $Eu(THD)_3$ Complexes in Solution"
J. Chem. Soc. Far. Trans. II, **73**, 545 (1977)

(14) H.G. Brittain and F.S. Richardson
"Circularly Polarized Emission Studies of Tb(III) and Eu(III) Complexes with Potentially Terdentate Amino Acids in Aqueous Solutions"
Bioinorg. Chem., 7, 233 (1977)

(15) G.L. Hilmes, H.G. Brittain, and F.S. Richardson
"Optical Activity of the $^4A_2 \leftrightarrow {}^2E$ Transition in $[Cr(en)_3]^{3+}$"
Inorg. Chem., **16**, 528 (1977)

(16) H.G. Brittain
"Hydroxynaphthol Blue as a Spectrophotometric and Fluorometric Reagent for the Uranyl Ion"
Anal. Lett., **10**, 263 (1977)

(17) H.G. Brittain
"Spectrophotometric Microdetermination of Alkaline Earth and Lanthanide Elements with Hydroxynaphthol Blue and Ethylenediaminetetraacetic Acid"
Anal. Chem., **49**, 969 (1977)

(18) R.W. Schwartz, H.G. Brittain, J.P. Riehl, W.C. Yeakel, and F.S. Richardson
"Magnetic Circularly Polarized Emission and Magnetic Circular Dichroism of the $^7F_J \leftrightarrow {}^5D_4$ Transitions in Crystalline $Cs_2NaTbCl_6$"
Mol. Phys., **34**, 361 (1977)

(19) H.G. Brittain
"Complex Formation Between Hydroxynaphthol Blue and First Row Transition Metal Cyanide Complexes"
Anal. Lett., **10**, 1105 (1977)

(20) H.G. Brittain
"Use of Hydroxynaphthol Blue in the Ultramicro Determination of Alkaline Earth and Lanthanide Elements: An improved Method"
Anal. Chim. Acta, **96**, 165 (1978)

(21) H.G. Brittain and F.S. Richardson
"Circular Dichroism and Absorption Spectra of Chiral Ketone:I_2 Complexes in Solution"
J. Chem. Soc. Far. Trans. II, **74**, 1151-1157 (1978)

(22) H.G. Brittain
"Binding of Transition Metal Ions by the Calcium Indicator Hydroxynaphthol Blue"
Anal. Lett., **11**, 355 (1978)

(23) H.G. Brittain
"Intermolecular Energy Transfer Between Lanthanide Complexes in Aqueous Solution. 1. Transfer from Tb(III) to Eu(III) Complexes of Pyridinecarboxylic Acids"
Inorg. Chem., **17**, 2762 (1978)

(24) H.G. Brittain
"Emission Intensity of Tb(III) Bound to Benzenecarboxylic Acid Derivatives"
J. Luminescence, **17**, 411 (1978)

(25) A. Recca, F. Bottino, P. Finocchiaro, and H.G. Brittain
"Static Stereochemistry of the β-Diketone Complexes of Group II Metals"
J. Inorg. Nucl. Chem., **40**, 1997 (1978)

(26) H.G. Brittain, G. Horozoglu, and A.D. Baker
"The He(I) Photoelectron Spectra of Some Substituted Co(III) Acetylacetonate Complexes"
J. Electron Spect. Rel. Phen., **16**, 107 (1979)

(27) H.G. Brittain
"Intermolecular Energy Transfer Between Lanthanide Complexes in Aqueous Solution. 2. Transfer from Tb(III) to Eu(III) Complexes of Phthalic and Hemimellitic Acids"
J. Inorg. Nucl. Chem., **41**, 561 (1979)

(28) H.G. Brittain
"Intermolecular Energy Transfer Between Lanthanide Complexes in Aqueous Solution. 3. Transfer from Tb(III) to Eu(III) Complexes of Trimellitic, Pyromellitic, and Trimesic Acids"
J. Inorg. Nucl. Chem., **41**, 567 (1979)

(29) H.G. Brittain
"Emission Titration Studies of the Adduct Formation Between Achiral Eu(III) β-Diketonates and Substrates"
J. Chem. Soc. Dalton Trans., 1187 (1979)

(30) H.G. Brittain
Cooperative Binding of Amine Substrate Molecules by Chiral Eu(III) Shift Reagents"
J. Am. Chem. Soc., **101**, 1733 (1979)

(31) H.G. Brittain
"Intermolecular Energy Transfer Between Lanthanide Complexes in Aqueous Solution. 4. Stereoselectivity in the Transfer from Tb(III) to Eu(III) Complexes of Aspartic Acid"
Inorg. Chem., **18**, 1740 (1979)

(32) H.G. Brittain
"Intermolecular Energy Transfer Between Lanthanide Complexes in Aqueous Solution. 5. Stereoselectivity in the Transfer from Tb(III) to Eu(III) Complexes of Malic Acid"
J. Inorg. Nucl. Chem., **41**, 721 (1979)

(33) H.G. Brittain
"Spectrophotometric Determination of Lanthanide Elements with the Calcium Binding Indicator Calmagite"
Anal. Chim. Acta, **106**, 401 (1979)

(34) H.G. Brittain
"Intermolecular Energy Transfer Between Lanthanide Complexes. 6. Influence of Metal-to-Ligand Ratio in the Transfer from Tb(III) to Eu(III) Complexes of L-Histidine"
J. Luminescence, **21**, 43 (1979)

(35) H.G. Brittain
"Solution Chemistry of Lanthanide Complexes. 1. Spectroscopic Studies of the Complexes Formed Between Lanthanide Ions and Hydroxyamino Acids"
J. Inorg. Nucl. Chem., **41**, 1775 (1979)

(36) H.G. Brittain
"Correlation of Circularly Polarized Luminescence Induced in $Tb(THD)_3$ by Chiral Solvents with the Absolute Configuration of those Solvents"
J. Am. Chem. Soc., **102**, 1207 (1980)

(37) Z. Konteatis and H.G. Brittain
"Stereoselectivity in Lanthanide Complexes of Malic Acid"
Inorg. Chim. Acta, **40**, 51 (1980)

(38) H.G. Brittain
"Solution Chemistry of Lanthanide Complexes. 2. Emission Titration Studies of the Adduct Formation Between Eu(III) β-Diketonate Complexes and Phosphate Esters"
Inorg. Chem., **19**, 640 (1980)

(39) H.G. Brittain
"Photodecomposition of the Tb(III) Chelate of 2,2,6,6-tetramethyl-3,5-heptanedione in Various Alcohol Solvents"
J. Phys. Chem., **84**, 840 (1980)

(40) H.G. Brittain
"Circularly Polarized Luminescence Studies of Mixed-Ligand Lanthanide Complexes Having the General Formula Tb(Pyridine-2,6-dicarboxylic acid)$_m$(L-Malic acid)$_n$, where m = 0-3 and n = 0-2"
Inorg. Chem., **19**, 2136 (1980)

(41) H.G. Brittain
"Circularly Polarized Luminescence Studies of the Ternary Complexes Formed Between Tb(III), Pyridine-2,6-dicarboxylic Acid, and Amino Acids"
J. Am. Chem. Soc., **102**, 3693 (1980)

(42) H.G. Brittain
"Solvent Dependence of the Circularly Polarized Luminescence Studies of the Tb(III) Chelate of 3-Acetyl-*d*-camphor"
Inorg. Chem., **19**, 2233 (1980)

(43) H.G. Brittain and D.L. Perry
"Luminescence Spectra of the Uranyl Ion in Two Geometrically Similar Coordination Environments: Uranyl Nitrate Hexahydrate and Di-μ-aquo-bis[dioxobis(nitrato)U(VI)]-diimidazole"
J. Phys. Chem., **84**, 2630 (1980)

(44) J.S. Madaras and H.G. Brittain
"Induced Optical Activity in the Tb(III) Complex of Pyridine-2,6-dicarboxylic acid Through Outer-Sphere Coordination with L-Ascorbic Acid"
Inorg. Chim. Acta, **42**, 109 (1980)

(45) H.G. Brittain
"Circularly Polarized Luminescence Studies of the Optical Activity Induced in the Eu(III) Chelate of 4,4,4-Trifluoro-1-(2-thienyl)-butane-1,3-dione Through Adduct Formation with Cinchona Alkaloids"
J. Chem. Soc. Dalton Trans., 2369 (1980)

(46) J.S. Madaras and H.G. Brittain
"Induced Optical Activity in the Tb(III) Complex of Pyridine-2,6-dicarboxylic acid Through Association with Resolved Tris(ethylenediamine)Cr(III)"
Inorg. Chem., **19**, 3841 (1980)

(47) H.G. Brittain
"Optical Activity Induced in Tris[4,4,4-trifluoro-1-(2-thienyl)-butane-1,3-dione] Eu(III) by Association with Chiral Amino Alcohols"
Inorg. Chem., **19**, 3473 (1980)

(48) H.G. Brittain, D.L. Ambrozich, M. Saburi, and J.H. Fendler
"Enhanced Optical Activity Associated with Chiral 1-[1-hydroxyhexyl]-pyrene Eximer Formation"
J. Am. Chem. Soc., **102**, 6372 (1980)

(49) F.S. Richardson and H.G. Brittain
"A Structural Study of Tris(β-diketonato) Eu(III) Complexes in Solution Using Magnetic Circularly Polarized Luminescence Spectroscopy"
J. Am. Chem. Soc., **103**, 18 (1981)

(50) A. Wallo and H.G. Brittain
"Photochemical Behavior of the Nd(III) and Ho(III) Complexes of Ethylenediaminetetraacetic Acid"
J. Inorg. Nucl. Chem., **43**, 561 (1981)

(51) H.G. Brittain
"Vicinal Effects Observed in the Circularly Polarized Luminescence Spectra of Mixed-Ligand Tb(III) Complexes"
Inorg. Chim. Acta, **53**, L7 (1981)

(52) H.G. Brittain
Circularly Polarized Luminescence Studies of Tb(III) Complexes of Hydroxycarboxylic Acids"
Inorg. Chem., **20**, 959 (1981)

(53) H.G. Brittain and Z. Konteatis
"Solution Chemistry of Lanthanide Complexes. 3. Spectroscopic Studies of Lanthanide Complexes of Glycine and Polyglycines"
J. Inorg. Nucl. Chem., **43**, 1719 (1981)

(54) Z. Konteatis and H.G. Brittain
"Solution Chemistry of Lanthanide Complexes. 4. Stability Constants of the 1:1 Complexes of Gd(III) with Glycine and Polyglycines"
J. Inorg. Nucl. Chem., **43**, 1675 (1981)

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Chapter 3.5, in ***Preformulation in Solid Dosage Form Development***, M.C. Adeyeye and H.G. Brittain, eds., Informa Healthcare Press, New York, 2008, pp. 253-277.

(284) H.G. Brittain
"Solubility Methods for the Characterization of New Crystal Forms"
Chapter 3.7, in ***Preformulation in Solid Dosage Form Development***, M.C. Adeyeye and H.G. Brittain, eds., Informa Healthcare Press, New York, 2008, pp. 323-346.

(285) H.G. Brittain
"Overview of the Solid Dosage Form Preformulation Program"
Chapter 4.1, in ***Preformulation in Solid Dosage Form Development***, M.C. Adeyeye and H.G. Brittain, eds., Informa Healthcare Press, New York, 2008, pp. 347-355.

(286) H.G. Brittain
"Methodology for the Evaluation of Chemical and Physical Interactions between Drug Substances and Excipients"
Chapter 4.3, in ***Preformulation in Solid Dosage Form Development***, M.C. Adeyeye and H.G. Brittain, eds., Informa Healthcare Press, New York, 2008, pp. 437-476.

Articles Currently in Press

(287) H.G. Brittain
"Polymorphism and Solvatomorphism 2006"
J. Pharm. Sci. (2008) **97**: in press.

(288) H.G. Brittain
"Photoluminescence of Pharmaceutical Materials in the Solid State. 4. Fluorescence Studies of Various Solvated and Desolvated Solvatomorphs of Erythromycin A"
for inclusion in ***Reviews in Fluorescence***, volume 4, C.D. Geddes and J.R. Lakowicz, eds., Springer, New York, 2008, pp. ???-???

Invited Presentations and Lectures of Harry G. Brittain, Ph.D.

(1) "New Methods for the Study of Optical Activity", presented during the symposium, *Molecular Optical Activity*, at the 2nd national meeting of the American Association of Pharmaceutical Scientists, Boston MA, June 11, 1987.

(2) "Spectral Methods for Determination of Water", presented during the symposium, *The Role of Moisture in Solid Dosage Forms*, at the 7th Wisconsin Update Conference, Madison WI, April 11, 1988.

(3) "The Scientific Aspects of Chirality: Principles", presented during the symposium, *Seminar on Chirality and Polymorphism*, organized by the Arnold & Marie Schwartz College of Pharmacy (Long Island University), Meadowlands, NJ, June 15, 1988.

(4) "The Scientific Aspects of Chirality: Consequences", presented during the symposium, *Seminar on Chirality and Polymorphism*, organized by the Arnold & Marie Schwartz College of Pharmacy (Long Island University), Meadowlands, NJ, June 15, 1988.

(5) "Physical Characterization of Pharmaceutical Materials", presented at the 12th Senior Technical Meeting of the Puerto Rico section of the American Chemical Society, San Juan PR, November 18, 1988.

(6) "Flowability Characterization of Nystatin Materials", presented at the 22nd annual Higuchi Research Seminar, Lake Ozark Missouri, March 14, 1989.

(7) "Raw Materials", presented during the symposium, *Scientific and Strategic Planning from IND to NDA*, at the 8th Wisconsin Update Conference, Madison WI, April 10, 1989.

(8) "The Scientific Aspects of Chirality: Consequences", presented during the, *Symposium on Chirality and its Impact on Drug Development*, at the 198th national meeting of the American Chemistry Society, Miami Beach, FL, September 14, 1989.

(9) "Chiroptical Studies of Pharmaceutical Compounds", presented during the symposium, *Circular Dichroism/Polarization*, at the 16th national meeting of the Federation of Analytical Chemistry and Spectroscopy Societies (FACSS), Chicago, IL, October 4, 1989.

(10) "Physical Characterization of Raw Materials", presented at the 13th Annual Conference of the Puerto Rico Pharmaceutical Quality Association, San Juan PR, January 30, 1990.

(11) "Physical Characterization of Pharmaceutical Excipients: Practical Examples", presented during the symposium, *Practical Aspects of Testing Excipients*, at the 5th national meeting of the American Association of Pharmaceutical Scientists, Las Vegas, NV, November 7, 1990.

(12) "Validation of Alternate Suppliers For Excipients", presented at the 14th Annual Conference of the Puerto Rico Pharmaceutical Quality Association, San Juan PR, January 29, 1991.

(13) "Solid-State Properties at the Molecular Level", presented during the symposium, *Solid-State Properties of Pharmaceutical Powders*, at the Pharm Tech Conference '91, New Brunswick, NJ, September 25, 1991.

(14) "Automating Non-Automatable Analytical Instruments", presented during the symposium, *Automation and Computer Assisted Analytical Methods*, at the 6th national meeting of the American Association of Pharmaceutical Scientists, Washington, D.C., November 18, 1991.

(15) "Analytical Techniques for When Things Go Wrong", presented during the symposium, *Drug Stability Issues in the 1990s*, at the 6th national meeting of the American Association of Pharmaceutical Scientists, Washington, D.C., November 20, 1991.

(16) "Excipient Issues, A User's Perspective", presented during the, *AAPS Workshop on the Development of Standards and Specifications in the 1990s*, Arlington, VA, February 20, 1992.

(17) "Physical Chemical Aspects of Functionality Testing of Raw Materials", presented during the symposium, *Pharmaceutical Validation*, organized by the Arnold & Marie Schwartz College of Pharmacy (Long Island University), East Brunswick, NJ, March 31, 1992.

(18) "Performance Characteristics Testing and Excipient Variability", presented at the 1992 International Industrial Pharmaceutical Research Conference, *Pharmaceutical Excipients: Characterization, Functionality, and Harmonization*, Merrimac, WI, June 10, 1992.

(19) "From Research to R&D to QC: Challenges of Method Transfer", presented during the symposium entitled *From Lab to Plant: Real World Challenges of Method Transfer*, at the 31st Eastern Analytical Symposium, Somerset, NJ, November 16, 1992.

(20) "Excipients: A Physico-chemical Perspective", presented during the symposium, *Excipients: Inert Ingredients or Functional Additives*, at the 7th national meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, November 18, 1992.

(21) "Solid State NMR and IR for the Analysis of Pharmaceutical Solids", presented at the 4th International Symposium on Pharmaceutical and Biomedical Analysis, Baltimore, MD, April 21, 1993.

(22) "Physical Characterization of Pharmaceutical Excipients", presented at the conference, *Tablet Manufacturing '93*, Morristown, NJ, April 27, 1993.

(23) "Characterization/Functionality Testing of Raw Materials", and, "Case Study on the Transfer of a Cream Formulation from the U.S. to the U.K.", both presented at the *AAPS/FDA/USP Workshop on the Scale-Up of Liquid and Semisolid Disperse Systems*, Arlington, VA, May 24, 1993.

(24) "Hydration and Solvation in Pharmaceutical Compounds: Structural Aspects", presented during the symposium, *Polymorphism and Spectroscopy*, at the 27th Middle Atlantic Regional Meeting of the American Chemical Society, Hempstead, NY, June 3, 1993.

(25) "Excipients: Functionality Testing and Vendor Qualifications", presented during the symposium, *Analytical Issues in Manufacturing*, at the 1st Annual PharmAnalysis Conference, East Brunswick, NJ, June 14, 1993

(26) "Specifications and Test Methods That Will Meet Regulatory Requirements", presented during the symposium, *Regulatory Compliance and the Drug Development Scientist*, at the 8th national meeting of the American Association of Pharmaceutical Scientists, Lake Buena Vista, Florida, November 15, 1993.

(27) "Functionality Testing of Pharmaceutical Excipients", presented at the Food and Drug Administration (at the invitation of the Chemistry, Manufacturing, and Controls Section), Rockville, MD, December 2, 1993.

(28) "Characterization of the Polymorphic Behavior in Pharmaceutical Solids by Solid-State NMR and IR", presented during the symposium, *Bioanalytical Chemistry, Pharmaceutical Analysis*, at the 45th meeting of the Pittsburgh Conference, Chicago, Illinois, March 1, 1994.

(29) "Characterization of Excipients", presented at the symposium, *Contemporary Issues in Formulation*, Wilmington, NC, May 24, 1994.

(30) "Circular Dichroism and Optical Rotatory Dispersion", presented during the symposium, *Chiroptical Spectroscopy: Molecular Dissymmetry Illuminated*, at the 2nd Annual PharmAnalysis Conference, Atlantic City, NJ, June 21, 1994.

(31) "Drug Products: An Industrial Perspective", presented at the, *AAPS Workshop on Impurities in Drug Substances and Products*, Arlington, VA, April 4, 1995.

(32) "Solid State NMR Spectroscopy for the Characterization of Pharmaceutical Solids", presented at the 6th International Symposium on Pharmaceutical and Biomedical Analysis, St. Louis, MO, April 24, 1995.

(33) "Chiroptical Spectroscopic Study of Pharmaceutical Compounds", presented at the 6th International Symposium on Chiral Discrimination, St. Louis, MO, April 28, 1995.

(34) "Physical Characterization of Excipients", presented during the symposium, *Pharmaceutical Excipients: Maker or Breaker of Pharmaceutical Dosage Forms*, at the 1995 Eastern Regional meeting of the American Association of Pharmaceutical Scientists, New Brunswick, NJ, June 6, 1995.

(35) "Characterization of Biomolecules: Vibrational Spectroscopy", presented during the symposium, *Biomolecular Spectroscopy*, at the 3rd Annual PharmAnalysis Conference, Atlantic City, NJ, June 19, 1995.

(36) "Effect of Processing Conditions on Crystal Properties of Drug Substances", presented at the, *AAPS/FDA Workshop on Polymorphism of Drug Substances*, Arlington, VA, February 27, 1996.

(37) "Impact of Analytical Technology Changes on the Pharmaceutical Industry", presented during the symposium, *Technology Changes: Impact on the Pharmaceutical Industry*, at the 16th Annual PharmTech Conference, East Rutherford, NJ, September 18, 1996.

(38) "Multi-Sourcing Excipients and Drug Substances", presented at the 16th Annual Eastern Pharmaceutical Technology Meeting, New Brunswick, NJ, November 15, 1996.

(39) "Chiroptical Spectroscopic Studies of Pharmaceutical Compounds", presented during the *Benedetti-Pichler Award Symposium* (honoring Professor D.W. Armstrong), at the Eastern Analytical Symposium, Somerset, NJ, November 21, 1996.

(40) "Effects of Processing on Solid-State Properties", presented at the 30th annual Higuchi Research Seminar, Lake Ozark Missouri, March 11, 1997.

(41) "Validation Studies for Non-Chromatographic Methods", presented at the *AAPS Workshop on Current Issues: Analytical Validation for the Pharmaceutical Industry*, Arlington, VA, April 7, 1998.

(42) "Polymorphism in Pharmaceutical Solids", presented to the Chemistry Department at Lehigh University, Bethlehem, PA, September 9, 1998.

(43) "Physical Characterization of Pharmaceutical Solids", presented at Magellan Laboratories, Inc., Research Triangle Park, NC, April 23, 1999.

(44) "Polymorphism in Pharmaceutical Solids", presented at Novartis, Inc., East Hanover, NJ, July 29, 1999.

(45) "Physical Characterization Techniques for Pharmaceutical Problem Solving", presented at the R.W. Johnson Pharmaceutical Research Institute 1999 Science Days, Delaware Valley College, Doylestown, PA, August 19, 1999.

(46) "Conventional and Unconventional Techniques for the Study of Pharmaceutical Chirality", presented at the R.W. Johnson Pharmaceutical Research Institute 1999 Science Days, Delaware Valley College, Doylestown, PA, August 19, 1999.

(47) "Physical Characterization Techniques for Pharmaceutical Problem Solving", presented to the School of Pharmacy at Rutgers University, Piscataway, NJ, September 13, 1999.

(48) "An Overview of Drug-Excipient Interactions in Dosage Forms, and its Implications in Development", keynote lecture presented during the symposium, *Drug-Excipient Interactions*, at the 1999 national meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November 18, 1999.

(49) "Factors Which Determine the Flowability of Powders", presented during the symposium, *Pharmaceutical Powders*, at the 1999 national meeting of the American Association of Pharmaceutical Scientists, New Orleans, LA, November 18, 1999.

(50) "System Suitability in Pharmaceutical Analysis: Powder Characterization Techniques", a plenary lecture presented during the USP Open Conference, *System Suitability in Pharmaceutical Analysis*, co-sponsored by the United States Food and Drug Administration and the United States Pharmacopoeia, Philadelphia, PA, December 6, 1999.

(51) "Techniques and Strategies for the Study of Solid-Solid Reactions", presented at Pfizer Inc., Groton, CT, January 14, 2000.

(52) "Validation of Non-Chromatographic Analytical Methodology", presented at the conference on *Stability Data Management*, Organized by the Center for Business Intelligence, Philadelphia, PA, February 1, 2000.

(53) "Characterization Methods for Fine Powders", presented at Pfizer Inc., Groton, CT, February 15, 2000.

(54) "Using Good Science to Smooth the Path for Pharmaceutical Scale-Up", presented to the North Carolina Pharmaceutical Discussion Group, Research Triangle Park, NC, February 16, 2000.

(55) "Development of Appropriate Investigational Techniques to Solve Problems of Pharmaceutical Interest", presented at Block Drug Company, Jersey City, NJ, March 21, 2000.

(56) "Materials and Materials Science in the Pharmaceutical Industry", presented at the 219th National Meeting of the American Chemical Society, San Francisco, CA, March 27, 2000.

(57) "Functionality Testing of Excipients", presented at the Midwest Regional Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, May 22, 2000.

(58) "Pharmaceutical Solids: Characterization of Bulk Drug Substances and Excipients, Functionality, Qualification, and Release", presented at Abbott Laboratories, Abbott Park, IL, May 23, 2000.

(59) "Application of the Phase Rule in the Characterization of Polymorphic Systems", presented at the conference on *Polymorphism and Crystallization*, Organized by Barnett International, Philadelphia, PA, June 15, 2000.

(60) "Use of Solid-State Spectroscopy for the Characterization of Polymorphs and Solvates", presented at the conference on *Polymorphism and Crystallization*, Organized by Barnett International, Philadelphia, PA, June 15, 2000.

(61) "Establishing Compendial Test Method Specification Harmonization", presented at the conference on *Excipient Formulation Strategies*, Organized by Barnett International, Philadelphia, PA, September 25, 2000.

(62) "Evaluation of the Relative Stability of Polymorphic Substances", presented to the School of Pharmacy at the University of Connecticut, Storrs, CT, October 5, 2000.

(63) "Physical Characterization of Pharmaceutical Materials at Various Stages in Development", keynote lecture presented during the symposium, *Drug Physical Properties of Pharmaceutical Solids and Their Impact on Processing Behavior and Performance of Dosage Forms*, at the 2000 national meeting of the American Association of Pharmaceutical Scientists, Indianapolis, IN, October 31, 2000.

(64) "Relative Stability of Polymorphic Systems", presented at Symyx Technologies, Santa Clara, CA, November 9, 2000.

(65) "Relative Stability of Polymorphic Systems", presented at Alkermes Inc., Cincinnati, OH, February 13, 2001.

(66) "Relative Stability of Polymorphic Systems", presented at Schering Plough Inc., Kenilworth, NJ, February 26, 2001.

(67) "Thermal Methods of Analysis", presented at Lavipharm Laboratories, East Windsor, NJ, April 30, 2001.

(68) "Incorporation of Stability-Indicating Physical Characterization Techniques in Stability Testing Programs", presented at the conference on *International Stability Programs*, Organized by the Center for Business Intelligence, Philadelphia, PA, June 15, 2001.

(69) "Powder Sampling; Flowability of Powdered Solids", presented at Alkermes Inc., Cincinnati, OH, July 9, 2001.

(70) "Materials and Materials Science in the Pharmaceutical Industry", presented at Malvern Instruments, Southborough, MA, August 17, 2001.

(71) "Particle Size Distribution in Pharmaceutical Materials", lecture presented as part of the symposium *Solid State Characterization in the Pharmaceutical Industry* at the 40th Eastern Analytical Symposium, Atlantic City, NJ, September 30, 2001.

(72) "X-Ray Powder Diffraction in the Pharmaceutical Industry", presented at the Annual Meeting of the International Centre for Diffraction Data, Newtown Square, PA, March 21, 2002.

(73) "Effects of Pharmaceutical Processing on Polymorphs", presented at the *Symposium on Polymorphism in Drug Substances and Drug Products*, organized as part of the Food and Drug Association Office of Generic Drugs Regulatory Science Training Series, Gaithersburg, MD, June 7, 2002.

(74) "Chemical and Physical Properties of Lactose", presented at the Annual Meeting of the International Food Technology Society, Anaheim, CA, June 17, 2002.

(75) "Use of Solid-State Spectroscopy for the Characterization of Polymorphs and Solvatomorphs", presented at the conference *Polymorphism and Crystallization*, Organized by Barnett International, Philadelphia, PA, June 21, 2002.

(76) "Functionality Testing of Excipient Materials", presented at the conference *Pharmaceutical Excipients*, Organized by Barnett International, Philadelphia, PA, June 28, 2002.

(77) "Polymorphism and Solvatomorphism: Overview of Science and Impact on Generic Companies", presented at the Fall Technical Workshop of the Generic Pharmaceutical Association, Bethesda, MD, October 15, 2002.

(78) "On Predictions of Physical Chemistry in the Preliminary-Preformulation stage of a Development Program", presented at the workshop on *Predictive Pharmaceutics*, Organized by ACD Laboratories, Toronto, Canada, November 10, 2002.

(79) "Physical Characterization of Compounds at the Early Development Stage", presented during the symposium, *Analytical Chemistry Challenges in Early Drug Development*, at the 2002 national meeting of the American Association of Pharmaceutical Scientists, Toronto, Canada, November 11, 2002.

(80) "Thermal Methods in Solid-State Characterization", presented during the Sunrise Pharmacy School, *Techniques in Solid-State Characterization*, at the 2002 national meeting of the American Association of Pharmaceutical Scientists, Toronto, Canada, November 12, 2002.

(81) "Critical Overview of the Proposed Particle Size Analysis Tests", presented during the symposium, *Excipient Functionality and Harmonization Update*, at the 2002 national meeting of the American Association of Pharmaceutical Scientists, Toronto, Canada, November 14, 2002.

(82) "Patent Litigation and X-Ray Powder Diffraction: A Tale of Two Solvatomorphs", presented at the 2nd Pharmaceutical Powder X-ray Diffraction Symposium, Concordville, PA, December 11, 2002.

(83) "Basis for Spectroscopic and Scattering Techniques", presented at the American Association of Pharmaceutical Scientists 38th Annual Pharmaceutical Technologies Conference at Arden House, Harriman, NY, January 29, 2003.

(84) "Crystallographic Basis for the Use of Thermal Analysis in the Characterization of Polymorphs and Solvatomorphs", presented at the American Chemical Society conference Polymorphism in Crystals: Fundamentals, Prediction and Industrial Practice, Tampa, FL, February 26, 2003.

(85) "Physical Characterization of Early Pharmaceutical Candidates and during API Development", presented at Albany Molecular Research, Albany NY, April 18, 2003

(86) "Particle Shape Factors and Nomenclature Issues", presented at the American Association of Pharmaceutical Scientists Workshop on Particle Size Analysis, Arlington, VA, April 30, 2003.

(87) "Use of Solid-State Spectroscopy for the Characterization of Polymorphs and Solvatomorphs", presented at the conference *Polymorphism and Crystallization*, Organized by Barnett International, Philadelphia, PA, June 6, 2003.

(88) "The Role of DSC in Preformulation: Then and Now", presented during the symposium, *Thermal Analysis of Pharmaceutical Materials*, at the 36th Middle Atlantic Regional Meeting of the American Chemical Society, Princeton, NJ, June 11, 2003.

(89) "Use of Thermal Methods of Analysis in the Characterization of Pharmaceutical Solids", presented at Albany Molecular Research, Albany NY, June 18, 2003.

(90) "X-Ray Powder Diffraction for Characterization of Pharmaceutical Solids", presented at Albany Molecular Research, Albany NY, August 28, 2003.

(91) "Application of Spectroscopy to Process Analytical Technology", presented during the conference, *TabletTech: Advances in Pharmaceutical Formulation and Processes*, sponsored by FMC Corporation, Princeton, NJ, November 12, 2003.

(92) "The Use Solid-State Fluorescence Spectroscopy for the Study of Polymorphism and Solvatomorphism", presented at the American Chemical Society conference *Polymorphism in Crystals*, Tampa, FL, February 11, 2004.

(93) "Establishing the Appropriate Salt Form for an Active Pharmaceutical Ingredient", presented at Albany Molecular Research, Albany NY, February 25, 2004.

(94) "Alternative Means for the Observation of Dissolution Phenomena", presented at the American Association of Pharmaceutical Scientists conference *Dissolution: New Technologies and Regulatory Initiatives*, Bethesda, MD, March 30, 2004.

(95) "Solubility Characterization of Polymorphs and Solvatomorphs", presented at the conference *Formulation and Process Development for Oral Dosage Forms*, Organized by Pharmaceutical Technologies International, Princeton, NJ, April 26, 2004.

(96) "Effects of Pharmaceutical Processing on Polymorphs and Solvatomorphs", presented at the conference *Formulation and Process Development for Oral Dosage Forms*, Organized by Pharmaceutical Technologies International, Princeton, NJ, April 26, 2004.

(97) "Incorporation of Solid-State Pharmaceutical Science during Drug Development", keynote lecture presented at the 36th Annual Pharmaceutical Graduate Student Research Meeting, Iowa City, Iowa, June 11, 2004.

(98) "Solubility Characterization of Polymorphic and Solvatomorphic Systems", presented at Albany Molecular Research, Albany NY, July 8, 2004.

(99) "Overview of Drug-Excipient Interactions in Pharmaceutical Dosage Forms", presented at the conference *Drug Excipient Compatibility*, Organized by Institute for International Research, Princeton, NJ, September 22, 2004.

(100) "Modern Applications of Differential Scanning Calorimetry in Preformulation", presented at the conference *Drug Excipient Compatibility*, Organized by Institute for International Research, Princeton, NJ, September 23, 2004.

(101) "Recent and Emerging Technologies for Excipient Characterization", presented at the conference *The Science of Quality*, Organized by the United States Pharmacopeia, Iselin, NJ, September 28, 2004.

(102) "Physical Characterization of Pharmaceutical Materials at Various Stages in Development", presented at Pfizer Inc., Groton, CT, October 5, 2004.

(103) "Emerging Techniques of Thermal Analysis for the Characterization of Pharmaceutical Solids", presented at Pfizer Inc., Groton, CT, October 5, 2004.

(104) "Selection Criteria, Structural Characterization, and Intellectual Property Aspects Associated with Salt Forms of a Drug Substance", presented at Vertex Pharmaceuticals, Cambridge, MA, October 14, 2004.

(105) "A Screening Protocol for the Detection of Polymorphs and Solvatomorphs", presented at Vertex Pharmaceuticals, Cambridge, MA, October 14, 2004.

(106) "Overview of the Characterization of Drug Substances and Drug Products at Various Stages During Development", presented at the Workshop *Recent Advances in Drug Substance and Drug Product CMC Information Requirements*, at the 2004 national meeting of the American Association of Pharmaceutical Scientists, Baltimore, MD, November 7, 2004.

(107) "Development of an Appropriate Salt Form: Strategies for Selection Criteria and Structural Characterization", presented at the conference *Preformulation / Formulation Strategies*, Organized by Barnett International, Philadelphia, PA, February 7, 2005.

(108) "Development of an Appropriate Salt Form: Strategies for Selection Criteria and Structural Characterization", presented at J.T. Baker – Mallinckrodt, Phillipsburg, NJ, April 1, 2005.

(109) "Understanding the Surface Acidity of Pharmaceutical Materials to Improve the Qualities of Formulations", presented at the conference *Hydrolysis and the Stabilization of Pharmaceuticals*, Organized by the Institute for International Research, Philadelphia, PA, July 28, 2005.

(110) "Validation Issues Associated with Thermal Methods of Analysis", presented at the 2005 USP Annual Scientific Meeting, *Impact the Future of Pharmacopeial Standards*, Organized by the United States Pharmacopeia, San Diego, CA, September 28, 2005.

(111) "Sampling Procedures that Yield Representative Input Materials for Physical Analyses", presented at the 2005 USP Annual Scientific Meeting, *Impact the Future of Pharmacopeial Standards*, Organized by the United States Pharmacopeia, San Diego, CA, September 29, 2005.

(112) "Physical Characterization of Pharmaceutical Drug Substances at Various Stages in Development", presented at the *API Characterization Workshop*, Organized by Johnson & Johnson Pharmaceutical Development, Princeton, NJ, November 3, 2005.

(113) "Effect of Particle Size on the Solubility and Dissolution Rate of Active Pharmaceutical Ingredients", presented at the *API Characterization Workshop*, Organized by Johnson & Johnson Pharmaceutical Development, Princeton, NJ, November 4, 2005.

(114) "Surface Acidity of Excipient Materials, and its Effect on Formulation stability", presented during the symposium, *Pharmaceutical Excipients –Analytical and Regulatory Development*, at the 2005 annual Eastern Analytical Symposium, Somerset, NJ, November 14, 2005.

(115) "Methods of Size Determination: A Discussion of the Effect of Particle Size on Dissolution Rates", presented at the conference *Dissolution – Moving Beyond Quality Control*, Organized by the Institute for International Research, Philadelphia, PA, January 25, 2006.

(116) "Stability-Indicating Physical Characterization Techniques in Programs of Stability Testing", presented at the conference *Drug-Excipient Compatibility Studies*, Organized by the Institute for International Research, Princeton, NJ, March 20, 2006.

(117) "Overview of Polymorphism and Solvatomorphism in Pharmaceutical Solids", presented at the Symposium *Characterization of Polymorphic Compounds and Mixtures*, at the fall 2006 national meeting of the American Chemical Society, San Francisco, CA, September 11, 2006.

(118) "Ionic Equilibria and the pH Dependence of Solubility", presented at the conference *Improving Solubility in Drug Candidates*, Organized by the International Quality and Productivity Center, Philadelphia, PA, September 19, 2006.

(119) "Use of Raman Spectroscopy for the Characterization of Excipients", presented at the 2006 USP Annual Scientific Meeting, *Impact the Future of Pharmacopeial Standards*, Organized by the United States Pharmacopeia, San Diego, CA, September 28, 2006.

(120) "An Overview of Solid-Solid Reactions and Their Relevance to Drug-Excipient Interactions", presented at the 2006 USP Annual Scientific Meeting, *Impact the Future of Pharmacopeial Standards*, Organized by the United States Pharmacopeia, San Diego, CA, September 29, 2006.

(121) "Strategy for Salt Selection for New Chemical Entities", presented at Alkermes Inc, Cambridge, MA, October 5, 2007.

Short Courses Taught by Harry G. Brittain, Ph.D.

(1) "Materials Science Methods for Solids Characterization", taught at the 27th Eastern Analytical Symposium, Somerset, NJ, October 4, 1988.

(2) "Polymorphism and Solid-State Properties of Pharmaceutical Solids", taught at the 7th national meeting of the American Association of Pharmaceutical Scientists, San Antonio, TX, November 15, 1992.

(3) "Physical Characterization of Pharmaceutical Solids", taught at the 6th International Symposium on Pharmaceutical and Biomedical Analysis, St. Louis, MO, April 23, 1995.

(4) "Stability Considerations", taught as part of the AAPS Short Course on Formulation Screening, at the 1997 AAPS Regional Meeting, New Brunswick, NJ, June 11, 1997.

(5) "Physical Characterization of Pharmaceutical Solids", taught at the 10th International Symposium on Pharmaceutical and Biomedical Analysis, Washington, DC, May 9, 1999.

(6) H.G. Brittain and D.E. Bugay, "Performance and Validation of Non-Chromatographic Compendial Methods", short course taught at the World Pharm 99 conference, Pennsylvania Convention Center, Philadelphia, PA, October 28, 1999

(7) "Physical Characterization of Pharmaceutical Solids", taught at Magellan Laboratories, Research Triangle Park, NC, April 14, 2000.

(8) "Pharmaceutical Solids: Characterization of Bulk Drug Substances and Excipients, Functionality, Qualification, and Release", taught at Abbott Laboratories, Abbott Park, IL, May 23, 2000.

(9) "Crystallography and X-Ray Diffraction", taught at Magellan Laboratories, Research Triangle Park, NC, October 24-25, 2000.

(10) "Thermal Analysis", taught at Magellan Laboratories, Research Triangle Park, NC, December 6, 2000.

(11) "Solid-State Vibrational Spectroscopy", taught at Magellan Laboratories, Research Triangle Park, NC, December 7, 2000.

(12) "Physical Characterization of Pharmaceutical Solids", a sequence of lectures taught at Smith-Kline-Beecham, King of Prussia, PA, over the period of 28 February through 16 October, 2000.

(13) "Solubility, Solubilization, and Dissolution Rate", taught at Magellan Laboratories, Research Triangle Park, NC, February 7-8, 2001.

(14) "Characterization of Pharmaceutical Solids: Solubility, X-Ray Powder Diffraction, and Solid-State Spectroscopy", short course taught over the Lehigh University Educational Satellite Network, Bethlehem, PA, March 15, 2001.

(15) "Particle Size Distribution", taught at Pfizer Global Research & Development Center, Groton, CT, April 5, 2001.

(16) "Polymorphism and Drug Crystal Structures", taught at the 40th Eastern Analytical Symposium, Atlantic City, NJ, September 30, 2001.

(17) "Side-Effects of Particle Size Reduction on the Physical Properties of Pharmaceutical Compounds", taught at the conference *Emerging Trends in Micronizing and Particle Size Reduction*, organized by Barnett International, Philadelphia, PA, June 23, 2003.

(18) "Review of the Impact of Spectroscopic Techniques on Process Analytical Technologies", taught at the conference *Process Analytical Technologies (PAT) Summit 2003*, organized by the Center for Pharmaceutical Training, Philadelphia, PA, September 29, 2003.

(19) "Establishing the Appropriate Salt Form for an Active Pharmaceutical Ingredient: Selection Criteria, Structural Characterization, and Intellectual Property Aspects", taught at the conference *Polymorphism and Crystallization Forum 2003*, organized by the Center for Pharmaceutical Training, Philadelphia, PA, November 10, 2003.

(20) "Developing an Appropriate Salt Form for an Active Pharmaceutical Ingredient: Strategies for Selection Criteria and Structural Characterization", taught at the conference *Salt Selection and Formulation/Pre-Formulation Strategies*, organized by Barnett International, Philadelphia, PA, March 1, 2004.

(21) "Physical Characterization of Pharmaceutical Solids", taught at Mutual Pharmaceuticals, Philadelphia, PA, October 22, 2004.

(22) "Developing Appropriate Salt Forms: Strategies for Selection Criteria and Structural Characterization", taught at the 4th annual conference *Polymorphism & Crystallization*, organized by the International Quality and Productivity Center, Philadelphia, PA, March 29, 2005.

(23) "Crystal Forms of Active Pharmaceutical Ingredients", taught at the conference *Formulation and Process Development for Oral Dosage Forms*, organized by Pharmaceutical Technologies International, Princeton, NJ, April 23, 2006.

(24) "Stability: Programs and Issues Related to the Quality of Solid dose Forms", co-taught with Professor Lynn Taylor at the conference *Formulation and Process Development for Oral Dosage Forms*, organized by Pharmaceutical Technologies International, Princeton, NJ, April 28, 2006.

(25) "Developing an Effective Preformulation Program", taught at the *PharmTech Annual Event* conference, organized by Pharmaceutical Technology and Advanstar Communications, Somerset, NJ, June 12, 2006.

(26) "Developing an Appropriate Salt Form: Strategies for Selection Criteria and Structural Characterization", taught in the School of Pharmacy at the University of Connecticut, Storrs, CT, February 6, 2007.

(27) "Crystal Forms of Active Pharmaceutical Ingredients", co-taught with Professor Raj Suryanarayanan taught at the conference *Formulation and Process Development for Oral Dosage Forms*, organized by Pharmaceutical Technologies International, Princeton, NJ, April 23, 2007.

(28) "Stability: Programs and Issues Related to the Quality of Solid dose Forms", co-taught with Professor Lynne Taylor at the conference *Formulation and Process Development for Oral Dosage Forms*, organized by Pharmaceutical Technologies International, Princeton, NJ, April 27, 2007.

(29) "Profiling an Active Pharmaceutical Ingredient for Formulation", taught at Merck & Co., West Point, PA, October 10, 2007.

(30) "Crystal Forms of Active Pharmaceutical Ingredients", co-taught with Professor Raj Suryanarayanan taught at the conference *Formulation and Process Development for Oral Dosage Forms*, organized by Pharmaceutical Technologies International, Princeton, NJ, April 28, 2008.

(31) "Stability: Programs and Issues Related to the Quality of Solid dose Forms", co-taught with Professor Lynne Taylor at the conference *Formulation and Process Development for Oral Dosage Forms*, organized by Pharmaceutical Technologies International, Princeton, NJ, May 2, 2008.